

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of:

Wen-Cherng Lee, et. al.

Confirmation No. 2278

Application: 10/510,459

Art Unit: 1625

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Examiner: Aulakh, Charanjit

Attorney Docket: 223255-120994

For: TRI-SUBSTITUTED HETEROARYLS AND METHODS OF MAKING AND
USING THE SAME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 C.F.R. § 1.705(b)(2)

1. This statement is submitted in support of the “Request for Reconsideration of Patent Term Adjustment Under 37 C.F.R. §1.705(d)” for the above-referenced patent application. It is respectfully requested that applicant be granted a patent term adjustment (hereinafter “PTA”) of 901 days.
2. The patent term adjustment according to the “Determination of Patent Term Adjustment Under 35 U.S.C. §154(b)” mailed on November 3, 2009 is 563 days. This determination is in error for the reasons discussed below, the correct number of days should be 901 days.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 C.F.R. §1.702 and §1.703

Pursuant to 37 C.F.R. §1.702 and §1.703, the period of adjustment of the term of the patent under §1.702 and §1.703 is the sum of the periods calculated under paragraphs §1.703 (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicant is entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 C.F.R. §1.703(a)(1), Applicant is entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months (*i.e.*, by October 25, 2006) after the actual filing date (hereinafter “14 Month Delay”). As shown on PAIR on the Office’s PTA Calculation Sheet, attached, the Office failed to mail an action under 35 U.S.C. § 132 (a Non-Final Rejection) until May 8, 2008. Applicant is entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after (*i.e.* October 25, 2006) the date on which the above-referenced application was filed or fulfilled the requirements under 35 U.S.C. § 371(c) (*i.e.*, August 25, 2005) and ending on the date of mailing of an action under 35 U.S.C. §132, (*i.e.*, May 8, 2008). Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 561 days, which is in agreement with the period calculated by the Patent Office.

(ii) “4 Month Delay” Pursuant to §1.703(a)(6)

In accordance 37 C.F.R. §1.703(a)(6), Applicant is entitled to a period of patent term adjustment for the number of days in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied (i.e. July 30, 2009) and ending on the date a patent was issued (i.e. November 3, 2009). Accordingly, the period of patent term adjustment due to the 4 Month Delay by the Office is 96 days, which is in agreement with the period calculated by the Patent Office.

(iii) “Three Years Delay” Pursuant to 37 C.F.R. §1.703(b)

Applicant submits that the Office did not comply with the requirement of 35 U.S.C. §154(b) and 37 C.F.R. §1.702(b), which requires issuance of a patent within 3 years after the date on which the patent application was filed under 35 U.S.C. §111(a). Accordingly, Applicant is entitled to an additional period of patent term adjustment beginning on August 26, 2008 (the day after the date that is three years after the date on which the above-referenced patent application was filed under 35 U.S.C. § 111(a)) and ending on the date the patent issued (i.e. November 3, 2009). This period from August 26, 2008 to November 3, 2009 is a period of 435 days.

On September 30, 2008, the U.S. District Court for the District of Columbia decided *Wyeth v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008). In *Wyeth*, the Court determined that the correct way to calculate PTA is to add any patent office delays that occur in the period of less than three years from the filing date (so called “A delay”) to any patent office delays that occur after three years from the filing date (so called “B delay”) in order to correctly determine the total number of days of PTA. In view of

Wyeth, Applicant submits that the captioned patent application is entitled to a total patent term adjustment of 901 days.

Under *Wyeth*, it is clear that delays under 35 U.S.C. §154(b)(1)(B) (and therefore under 37 C.F.R. §§1.702(b) and 1.703(b)) begin when the USPTO has failed to issue a patent within three years, subject to the exclusions of 35 U.S.C. §154(b)(1)(B)(i)-(iii). In the captioned patent application, the period of adjustment under 37 C.F.R. §1.703(a)(1), ending on May 8, 2008, clearly does not overlap with the period of adjustment under 37 C.F.R. §1.703(b) which started on August 26, 2008. As the period of adjustment under 37 C.F.R. §1.703(b)(6), beginning on July 30, 2009, does overlap with the period of adjustment under 37 C.F.R. §1.703(b), beginning on August 26, 2008, applicant has not requested adjustment for this 96 day period. Accordingly, Applicant is entitled to the period of adjustment under 37 C.F.R. §§ 1.703(a)(1) and 1.703(b), rather than using the Patent Office calculation which fails to include the 434 day delay after 3 years from filing or fulfilling the requirements under 35 USC 371(c). As such, Applicant is entitled to a total patent term adjustment (PTA) of 901 days.

(iv) Total Examination Delay Pursuant to 37 C.F.R. §1.703

As set forth in 37 C.F.R. §1.703, the period of examination delay based on the grounds set forth in 37 C.F.R. §1.702 is the sum of the period of change from the 14 Month Delay (561 days) and the maximum period of Three Years Delay (434 days), resulting in a total of 995 days, which periods of delay are not overlapping.

B. “Applicant Delay” Pursuant to 37 C.F.R. §1.704

Pursuant to 37 C.F.R. §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the

PTO's Patent Term Adjustment calculation on PAIR, the Office has calculated a period of Applicant Delay of 94 days.

(i) Applicant Delay for Responding to Restriction Requirement Dated May 8, 2008

Applicant respectfully submits that one period of Applicant Delay of 94 days accrued for the delayed filing of a Response on November 10, 2008. This is consistent with the Patent Term Adjustment calculation shown on PAIR, from the Office. Accordingly, pursuant to 37 CFR § 1.704(b), this 94 day period should be considered an Applicant Delay.

(ii) Calculation of the Total Period of Applicant Delay

In view of the above, applicant has calculated a total period of Applicant Delay of 94 days which consists of (i) the 94 day period. Accordingly, the total period of this delay is 94 days, which is in agreement with the period calculated by the Office on the PTA Calculation Sheet for Patent Term Adjustment calculation and on PAIR.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. §1.703 to §1.705

As set forth in 37 C.F.R. §1.704, applicant is entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicant submits that the correct patent term adjustment for the above-referenced patent application is 901 days, which is the difference between the total period of examination delay (995 days) less the Applicant Delay (94 days).

4. In accordance with 37 C.F.R. §1.705(b)(2)(iii), Applicant submits that this patent application is not subject to a terminal disclaimer.

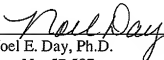
5. In accordance with 37 C.F.R. §1.705(b)(2)(iv)(A) and (B), Applicant does not believe there were any circumstances where there was a failure to engage in reasonable efforts to conclude processing or examination of this application as is set forth in § 1.704.

In view of the foregoing, it is respectfully requested that the Application for Patent Term Adjustment and the facts provided in this Statement of Facts be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment (PTA) of 901 days.

Respectfully submitted,

By: Honigman Miller Schwartz and Cohn LLP

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